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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,389	10/02/2003	Giorgio Soldani	36159	9553
116	7590	11/23/2005	EXAMINER	
PEARNE & GORDON LLP 1801 EAST 9TH STREET SUITE 1200 CLEVELAND, OH 44114-3108			CAMERON, ERMA C	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 11/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/677,389

Applicant(s)

SOLDANI, GIORGIO

Examiner

Erma Cameron

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 10-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 10/24/2005.

### *Specification*

2. Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

3. The disclosure is objected to because of the following informalities:

6:29 and 11:18 - typos

Appropriate correction is required.

***Drawings***

4. There is no Brief Description of the Drawings.

Correction is requested.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

“...oxygen free atmosphere...” is not described in the specification as originally filed.

7. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparing an elastomeric material that is 20-40% polydialkylsiloxane, does not reasonably provide enablement for any level of polydialkylsiloxane. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

See 13:34-17:32. It appears that the claimed invention requires 20-40% PDMS (17:24-26). Siloxane outside these ranges appears to give inferior results.

8. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

12:14-16 It is not clear what "material" (used twice) is meant here, the claimed invention or Cardiothane?

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a) Claim 5: it is not clear if the polyurethane of claim 5 is the same or different from the polyurethane of claim 1.
- b) Claim 6: it is not clear if the polydialkylsiloxane of claim 6 is the same or different from the polydialkylsiloxane of claim 1.
- c) Claim 6: it is not clear what is meant by the plurality of polydimethylsiloxanes. In what way do these siloxanes exist as a plurality?
- d) Claim 7: it is not clear if the polydimethylsiloxane of claim 7 is the same or different from the polydimethylsiloxane of claim 6.
- e) Claim 8: it is not clear if the polydimethylsiloxane of claim 8 is the same or different from the polydimethylsiloxane of claim 7.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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12. Claims 1-2 and 4-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Nyilas (3562352).

'352 teaches making an elastomeric copolymer by reacting, in the absence of air, polyether polyurethane or polyester polyurethane and acetoxy end blocked polydimethylsiloxane in the presence of a solvent such as THF and dioxane at 40-50 degrees C for 6 to 10 hours (2:40-6:51). The polydimethylsiloxane has 8 terminal acetoxy groups, which is inclusive of the 1-4 or 4 terminal acetoxy groups claimed by applicant (5:74-75).

13. Claims 1-3, 6 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kira (4623347).

'347 teaches making an elastomeric antithrombogenic copolymer by reacting a polyurethane and polydimethylsiloxane at under 100 degrees C in a mixed solvent and under nitrogen (see Examples 1 and 2; 5:53-67).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nyilas (3562352) taken in view of Kira (4623347).

'352 is applied here for the reasons given above.

'352 teaches excluding air but fails to teach excluding oxygen by using nitrogen.

'347 teaches reacting a polyurethane and polydimethylsiloxane, as does '352, and doing so in nitrogen atmosphere (see Examples 1 and 2).

It would have been obvious to one of ordinary skill in the art to have used the nitrogen atmosphere of '347 in order to exclude air from the '352 process.

16. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kira (4623347).

'347 is applied here for the reasons given above.

It is somewhat ambiguous in '347 what the length of the reaction time is.

It would have been obvious to one of ordinary skill in the art to have optimized the reaction time through no more than routine experimentation because reaction time is known to be an important parameter to control in chemical reactions.

### ***Conclusion***

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.



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18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on 8:30-6:00, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ERMA CAMERON  
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November 18, 2005